



# Should TrimSpa X32 Remain on the Market? An analysis of TrimSpa X32's compliance with FDA and FTC guidelines

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## **Should TrimSpa X32 Remain on the Market?**

An analysis of TrimSpa X32's compliance with FDA and FTC guidelines

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Class of 2005  
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This paper is submitted in satisfaction of the course requirement.

## **ABSTRACT**

TrimSpa X32 has launched onto the dietary supplement and weight loss markets with a deluge of promotion, from a celebrity endorser to a million dollar contest, from sponsorship of award shows to a website filled with information, testimonials, and a personal consultation tool. But is the product safe and are the advertisements for the product truthful and nonmisleading? This paper examines TrimSpa X32 to determine whether it complies with the applicable regulatory guidelines of both the United States Food and Drug Administration (FDA) and United States Federal Trade Commission (FTC). In order to do so, this paper first analyses the Dietary Health and Supplement Act of 1994 which provides the basis for FDA regulations and “Dietary Supplements: An Advertising Guide for Industry” which sets out guidelines to aid the FTC in regulating the advertising of dietary supplements and also provides a comprehensive guide to advertisers to aid them in complying with FTC regulations. This paper concludes that TrimSpa currently complies with all applicable regulations. However, there are several issues which may arise in the future, including safety and efficacy concerns and potential claims of misleading advertisements and duty-to-warn litigation.

## **INTRODUCTION**

Americans are fat and have consistently become fatter over the past twenty years.<sup>1</sup> However, consumers’ realization of the health risks of obesity and societal pressure for slimmer bodies has generated a new problem:

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<sup>1</sup>See Rob Stein, *Fidgeting Helps Separate the Lean From the Obese, Study Finds*, The Washington Post, Jan. 28, 2005, at A2, reporting that two-thirds of Americans are overweight; *See also*, National Center for Chronic Disease Prevention and Health Promotion, U.S. Obesity Trends 1985-2003.

an obsession with weight loss. This obsession has launched a fifty billion dollar weight loss industry.<sup>2</sup> Americans have been bombarded with new diet plans, diet foods, and diet drugs. While many debate the merits of Weight Watchers, Jenny Craig, the South Beach Diet, and the Atkins Diet, it appears that Americans have embraced these tools as means to the same end: weight loss. But, is the fast-food culture willing to accept long-term solutions requiring exercise, portion control, and nutritionally balanced meals? Perhaps Americans do not have the time for such measures or, just as they prefer a quick meal on the go, they prefer a quick fix. In the spirit of the free market, businesses have attempted to sate America's love of quick, easy solutions with the introduction of weight loss drugs.

One quick and easy solution arrived in the form of "fen-phen". Unfortunately, fen-phen, a combination of two different drugs, fenfluramine and phentermine, caused the deaths of several users.<sup>3</sup> Nevertheless, even after the fen-phen disaster rode the front pages of newspapers across the country, American dieters wanted the "next best thing" and sought out weight loss alternatives, including herbal fen-phen substitutes and other herbal remedies. Such remedies often include ephedrine/ephedra (which has since been taken off the market), St. Johns Wort, and other herbal ingredients.<sup>4</sup> One such remedy, TrimSpa X32, has now hit the market with a big splash – endorsed by a celebrity and backed by a "Million Dollar Makeover Challenge" to customers.<sup>5</sup> For a mere \$39.95 per bottle<sup>6</sup>, consumers can shed pounds quickly and be overweight no more. Television commercials for TrimSpa X32 feature a newly svelte Anna Nicole Smith proclaiming the benefits of this new herbal weight loss remedy and its website declares that TrimSpa X32 is #1 in Hoodia

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<sup>2</sup>*Infomercial launched to test market weight loss product*, Obesity, Fitness & Wellness Week, February 5, 2005, at 1556.

<sup>3</sup>Jennifer Sardina, *Misconceptions and Misleading Information Prevail – Less Regulation does not Mean Less Danger to Consumers: Dangerous Herbal Weight Loss Products*, 14 Clev. St. J.L. and Health 107, 108 (1999/2000).

<sup>4</sup>*Id* at 108-110.

<sup>5</sup>See <http://www.trimspa.com>

<sup>6</sup><http://www.trimspa.com/main/buy.shtml>

gordonii. But, is this truly the answer to the United States' growing obesity problem? Do consumers even know what Hoodia gordonii is? The question remains as to whether this product is safe and whether it should be allowed on the market. This paper examines the basis for FDA and FTC regulation of herbal remedies and explores whether TrimSpa X32 is in compliance with the applicable regulations, and finally whether it should remain on the market.

## **REGULATION OF HERBAL AND DIETARY SUPPLEMENTS**

### **I. Food and Drug Administration**

Approximately twenty-five years ago, Congress debated the nature and strength of regulations necessary for the \$15 billion a year herbal and dietary supplement industry.<sup>7</sup> Enormous grassroots and lobbyist pressure encouraged Congress to create a new FDA-regulated category for supplements, separate from both drugs and food. The new statute, Dietary Supplement Health and Education Act of 1994 (DSHEA), was the result of Congress' findings that "dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare" and "legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness."<sup>8</sup> The DSHEA's new class of products includes vitamins, minerals, herbs, botanicals, amino acids, and "dietary substance[s] for use by man to supplement the diet by increasing the total dietary intake."<sup>9</sup> This definition includes such

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<sup>7</sup>Trisha L. Beckstead, *Comment: Caveat Emptor, Buyer Beware: Deregulation of Dietary Supplements Upon Enactment of the Dietary Supplement Health and Education Act of 1994*, 11 S.J. Agri. L. Rev. 107 (2001).

<sup>8</sup>Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, §2, 108 Stat. 4325 (1994) (codified at 21 U.S.C. § 321 (2005)).

<sup>9</sup>21 U.S.C. § 321(ff) (2005).

products as fish oil, ginseng, and the aforementioned ephedra and St. John's Wort.<sup>10</sup>

The DSHEA not only created a new class of products but devised a new regulation scheme which the FDA must follow. In contrast to new drugs and new food ingredients, supplements are not subject to premarket approval.<sup>11</sup> Manufacturers can introduce products to the market without testing them for safety or effectiveness. Further, based upon Congressional findings, the assumption must be that the herbal products are safe for the public. The FDA, rather than manufacturers in the case of new food ingredients or drugs, maintains the burden of proof for safety examinations.<sup>12</sup> The FDA may force dietary supplements off the market only in cases where the products pose an "imminent hazard to the public health and safety."<sup>13</sup> The lag between market introduction and FDA action allows potentially harmful products to be in consumers' hands for extended periods of time.

The FDA maintains oversight over not only a product's ingredients but also its labeling. The DSHEA provides the FDA with such authority over dietary supplements and sets out specific labeling standards for these products. Dietary supplements may only make statements which claim "a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States", describe "the role of a nutrient or dietary ingredient intended to affect the structure or function in humans," characterize "the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or

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<sup>10</sup>U. S. FDA Center for Food Safety and Applied Nutrition, *Dietary Supplement Health and Education Act of 1994* (1995), available at <http://vm.cfsan.fda.gov/~dms/dietsupp.html>.

<sup>11</sup>Donna V. Porter, *Dietary Supplement Health and Education Act of 1994: P.L. 103-417*, Nutrition Today, April 1995, available at [http://www.findarticles.com/p/articles/mi\\_m0841/is\\_n2.v30/ai\\_16904364](http://www.findarticles.com/p/articles/mi_m0841/is_n2.v30/ai_16904364).

<sup>12</sup>*Id.*

<sup>13</sup>21 U.S.C. §342(f)((1)(C) (2005).

function,” or describe “general well-being from consumption of a nutrient or dietary ingredient.”<sup>14</sup> Therefore, manufacturers must limit their statements to either nutritional deficiency, structure-function, or well-being claims. However, any statement must also include a prominently displayed disclaimer that the product is not evaluated by the FDA nor “is not intended to diagnose, treat, cure, or prevent any disease.”<sup>15</sup> If a claim is made that the dietary supplement *does* intend to diagnose, treat, cure or prevent a disease, then the manufacturer must notify the FDA of such a statement within thirty days after first marketing the product.<sup>16</sup> Finally, and perhaps most importantly, any statement made by the manufacturer on the product must be truthful and not misleading.<sup>17</sup>

One further measure of power provided by the DSHEA is the regulation of new ingredients. A new ingredient in a dietary supplement is considered “adulterated” (and so may not remain on the market) unless the “dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered” or “[t]here is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe” and the manufacturer submits proof of such reasonable expectation of safety to the FDA.<sup>18</sup> The DSHEA therefore allows a “grandfather exemption” to any drugs which have already been on the market. Even if a manufacturer creates a new use or dosage for that ingredient, if it has already been in use and there is a reasonable expectation of safety, then the DSHEA allows it to be introduced for public sale.

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<sup>14</sup>21 U.S.C. § 343(r)(6)(A) (2005).

<sup>15</sup>21 U.S.C. § 343(r)(6)(C) (2005).

<sup>16</sup>*Id.*

<sup>17</sup>21 U.S.C. § 343(r)(6)(B) (2005).

<sup>18</sup>21 U.S.C. §350b(a) (2005)

## **II. Federal Trade Commission**

Although the DSHEA institutes several regulatory provisions for dietary supplements, including FDA oversight for product labeling, it does not address product advertisements. The Federal Trade Commission possesses authority over the advertising of food, drugs, and herbal supplements. The Federal Trade Commission Act prohibits “unfair or deceptive acts or practices” and “any false advertisement” of food products that is “misleading in a material respect.”<sup>19</sup> Further, the FTC’s publication, “Dietary Supplements: An Advertising Guide for Industry,” adds an additional requirement that an advertiser possess “adequate substantiation for all objective product claims (before the advertisement is disseminated).”<sup>20</sup>

In determining whether an advertisement fails to be truthful or nonmisleading, the FTC analyzes the statements based on both explicit and implicit claims.<sup>21</sup> Such an examination includes interpretations of the claims based on the contexts of the advertisements and a consideration of both what is explicitly stated and what information is *not* included. In order to ensure that statements are not misleading, the FTC has advised manufacturers to “use clear language, avoid small type, place qualifying information close to the claim, and avoid making inconsistent statements or including distracting elements that undercut the disclosure.”<sup>22</sup>

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<sup>19</sup>Robert G. Pinco and Todd H. Halpern, *Guidelines for the Promotion of Dietary Supplements: Examining Government Regulation Five Years After Enactment of the Dietary Supplement Health and Education Act of 1994*, 54 Food Drug L.J. 567, 580 (1999).

<sup>20</sup>U.S. Federal Trade Commission, *Dietary Supplements: An Advertising Guide for Industry* (1998), available at <http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>.

<sup>21</sup>*Id.*

<sup>22</sup>*Id.*



The addition of a requirement of substantiation for dietary supplement advertisements imposes a duty on advertisers to possess “competent and reliable scientific evidence” to support each and every claim.<sup>23</sup> While the proper level of substantiation is determined on a case-by-case basis, it is based upon the FTC’s determination of the amount of substantiation normally relied upon by researchers in the particular, and similar, fields of study.<sup>24</sup> Such factors considered by the FTC include “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”<sup>25</sup> Customer testimonials are generally not enough to constitute support for a specific product claim.<sup>26</sup> While it is unclear whether a manufacturer must be conduct studies to prove that its specific product is effective and supports any advertised claims, rather than relying on established studies of similar products, it appears that the FTC is leaning towards imposing such a requirement.<sup>27</sup> *Therefore, although a product may be nearly identical to a competitor’s and that competitor has published efficacy studies,* reliance on that competitor’s research may not be enough for a product to satisfy an FTC claim for lack of substantiation.

The FTC also reviews customer testimonials in determining whether the advertisement is both truthful and non-misleading. Not only are such testimonials insufficient to substantiate a claim made by the advertiser, a “clear and conspicuous disclaimer” must appear on the advertisement.<sup>28</sup> Further, the “advertiser should either state what the generally expected results would be or indicate that the consumer should not expect

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<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> Pinco and Halpern, 54 Food Drug L.J. at 582-583.

<sup>28</sup> U.S. FTC, *Dietary Supplements: An Advertising Guide for Industry*.

to experience the attested results. Vague disclaimers like ‘results may vary’ are likely to be insufficient.”<sup>29</sup> A disclaimer must provide information such as whether the results promoted by the testimonial are similar to results expected to be experienced by other users and, if not, what a consumer should expect to gain (or lose) from consuming the product.

Finally, while the two-part DSHEA disclaimer, This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease, applies only to product labeling and not to advertising, the FTC has promoted its use when statements made by the advertiser may be misleading to consumers.<sup>30</sup> If the advertisement leads consumers to believe that the FDA has conducted studies on the safety or efficacy of the product or somehow approved its use, the advertiser must use the two-part disclaimer.<sup>31</sup> However, mere use of the disclaimer does not provide a substitute for the claim substantiation and truthfulness requirements of the FTC.<sup>32</sup>

### **ANALYSIS OF TRIMSPA**

TrimSpa X32 is one of the newer and more heavily advertised herbal weight loss products on the market today. The manufacturer of TrimSpa X32 has launched an intense promotional campaign with Anna Nicole

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<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

Smith as celebrity endorser and is currently promoting a “Million Dollar Makeover Challenge” for its product. Further, the manufacturer of TrimSpa X32 has produced numerous television advertisements for the product, sponsored charity and promotional events, and maintains a colorful website with information about the product, customer testimonials, and, of course, a “Buy Now” feature. However, one must question whether this product is safe and effective and whether its advertising satisfies FTC requirements for truthfulness and substantiation.

## **I. Two “Primary” Ingredients**

It appears from TrimSpa’s advertising and information on its website that the TrimSpa X32 product relies on two primary ingredients to produce the touted weight loss results: Hoodia gordonii and glucasomine. While TrimSpa X32 contains numerous other ingredients, such as gucomannan, green tea extract and cocoa extract, consumers are led to believe that these ingredients are supplementary to the more powerful effects of Hoodia gordonii and glucasomine. Therefore, this paper will analyze the two “primary” ingredients of TrimSpa X32.

### **a. Hoodia Gordonii**

The most heavily touted ingredient in TrimSpa X32 is Hoodia gordonii. Although it is the third in terms

of quantity, it is first in terms of advertised benefits to the consumer.<sup>33</sup> It is the first ingredient listed as part of the TrimSpa X32 “formula”<sup>34</sup> and TrimSpa’s homepage touts the product as “#1 in Hoodia gordonii.”<sup>35</sup> The manufacturer of TrimSpa X32 claims that the primary ingredient in the product “to help achieve create a sexier you” is Hoodia gordonii, which is “a natural appetite suppressant, used for generations by South African tribesmen to stave off hunger during long hunting expeditions.”<sup>36</sup> While Hoodia gordonii is relatively new to the Western World, it has, as stated by TrimSpa, been used for many years by South African hunters.<sup>37</sup> However, such use may or may not translate to the weight loss benefits sought by American consumers. Because the DSHEA does not require premarket approval or safety and efficacy testing prior to introduction to the market, one cannot be sure that use of Hoodia gordonii via TrimSpa X32 is both safe and effective. While small-scale studies have reported that both rats and humans lost their appetites while taking Hoodia gordonii without experiencing side effects,<sup>38</sup> no manufacturer or research body has published a large-scale study as to the safety and efficacy of Hoodia gordonii.<sup>39</sup> One major consumer products company, Unilever, has announced a multi-stage research program to analyze the safety and efficacy of Hoodia gordonii.<sup>40</sup> However, it will likely take a great amount of time before the program is completed and consumers may look to a formal study as to whether Hoodia gordonii actually works appropriately as a safe weight loss supplement.

Yet, certain dangers of using Hoodia gordonii have already been reported. Not only does Hoodia gordonii

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<sup>33</sup>See, [http://www.TRIMSPA.com/main/cef\\_ingredients.shtml](http://www.TRIMSPA.com/main/cef_ingredients.shtml); <http://www.trimspa.com/main/cef.shtml>

<sup>34</sup><http://www.TRIMSPA.com/main/cef.shtml>

<sup>35</sup><http://www.TRIMSPA.com>

<sup>36</sup><http://www.TRIMSPA.com/main/cef.shtml>

<sup>37</sup>*Id.*

<sup>38</sup>Michael Hanlon, *The Cactus Diet*, Daily Mail, December 17, 2004, at 15.

<sup>39</sup>Hilary E. MacGregor, *African Plant Can Suppress Hunger for Days, But is it Safe?*, L.A. Times, November 29, 2004, at F1.

<sup>40</sup>*Id.*

turn off the one's appetite, it also suppresses a user's thirst.<sup>41</sup> This lack of thirst could result in dehydration and possibly death in users of Hoodia gordonii. Further, one doctor reported that Hoodia gordonii "was not supposed to make you lose weight; it was supposed to allow you to hunt successfully in a difficult environment. It's not unsafe, used the way it was traditionally. But I don't think we have any experience with Hoodia and obesity."<sup>42</sup> Nevertheless, because no study exists as to the safety and efficacy of Hoodia gordonii, the FDA cannot use such statements as "proof" that TrimSpa X32 must be removed from the market. The FDA maintains the burden of proof as to whether the product presents an imminent safety hazard to consumers. It is doubtful that the potential dangers of dehydration and the potential for harm in this new use of Hoodia gordonii would be enough to reach that burden. Further, the description of Hoodia gordonii as a "natural appetite suppressant" is neither false nor misleading and so follows the applicable FDA regulations under the DSHEA.

While Hoodia gordonii is "new" in terms of its use in the United States, there is ample evidence as to its safe and prolonged use in its native country. While the manufacturer of TrimSpa X32 may be able to argue that such use presents evidence as required by the grandfather clause of the DSHEA, one may argue that the history of use was *not* under the same conditions and dosage of TrimSpa X32. Even assuming that the manufacturer of TrimSpa X32 followed the reporting guidelines of the grandfather clause, it is possible that TrimSpa X32 fails on the use and dosage requirement. Hoodia gordonii *has* been used in other products, such as teas,<sup>43</sup> but there remains a question of how long such products have been in the food supply and in what dosage.

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<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

## **b. Glucosamine**

The second ingredient listed in the TrimSpa X32 “formula”, though sixth in terms of quantity, is glucosamine.<sup>44</sup> TrimSpa’s website describes this ingredient as “an ingredient, patented by TRIMSPA for weight loss, that actually prolongs the amount of time glucose (or blood sugar) stays within the bloodstream after eating. This delay means that any extra insulin can be used directly by the muscles for energy, instead of being transferred too quickly to the ‘warehouse,’ or fat cells.”<sup>45</sup> Studies as to the effectiveness of the use of glucosamine for weight loss have been inconclusive. While some studies have shown modest benefits, others have not shown any benefits related to glucosamine use.<sup>46</sup> However, studies have shown that it does not “appear harmful or to interact negatively with other medications.”<sup>47</sup>

Rather than being used for weight loss, glucosamine is primarily promoted for the treatment of arthritis, “relieving osteoarthritis pain and slowing the degredation of joint cartilage”.<sup>48</sup> Such use could fall within the DSHEA new ingredient grandfather clause, but it may run afoul of the same “conditions of use” and dosage issues as Hoodia gordonii. But, this is not the only problem with glucosamine. The FDA could cite the lack of studies which show significant benefits to consumers seeking weight loss as evidence of false and misleading statements. However, FDA retains the burden of proof and the existence of studies showing

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<sup>44</sup>See, <http://www.trimspa.com/main/cef.shtml>; [http://www.trimspa.com/main/cef\\_ingredients.shtml](http://www.trimspa.com/main/cef_ingredients.shtml)

<sup>45</sup><http://www.trimspa.com/main/cef.shtml>

<sup>46</sup>Celeste Robb-Nicholson, *Health for Life M.D.: Our Doctor’s Advice*, Newsweek Web Exclusive, May 2, 2004.

<sup>47</sup>*Id.*

<sup>48</sup>Celeste Robb-Nicholson, *By the Way, Doctor: Does Glucosamine Cause Diabetes*, Harvard Women’s Health Watch, Jan. 1, 2005.

modest benefits may be enough to defeat such a claim. Finally, the use of glucosamine has been shown to increase blood sugar levels in diabetics and increase the body's resistance to insulin. These effects present potential health risks to consumers, especially if they are diabetic. While the labeling on TrimSpa X32 does inform consumers with a disclaimer, "Health Concerns: Do not take if you are a diabetic," the statement appears within a litany of other disclaimers and may not be easily noted by diabetic consumers.<sup>49</sup> If the FDA can find and report studies which document such risks and prove that the existence of such risks presents a significant health risk to consumers, then it is possible for the FDA to pull TrimSpa X32 from the market.

## **II. Compliance with Additional DSHEA Regulations**

Although this paper has addressed whether or not the FDA can force TrimSpa X32 off the market due to safety concerns, there are several other regulations required by the DSHEA. First, TrimSpa X32 must comply with the appropriate labeling requirements. These requirements include labeling the product as a dietary supplement and listing the name of each ingredient, the quantity of each ingredient, the total quantity of ingredients in the product, and the name and part of the plant each applicable ingredient is derived.<sup>50</sup> TrimSpa X32's label fulfills numerous facets of the labeling requirements. All ingredients are identified, the applicable plant name and part (for *Hoodia gordonii*) is listed, and amount of each ingredient per serving is noted. Further, it lists on the front of the bottle that it is a "dietary supplement." However, TrimSpa X32 does not list the total quantity of dietary supplement ingredients. Therefore, it is not technically in compliance with DSHEA and is subject to appropriate sanctions by the FDA.

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<sup>49</sup> See, <http://www.trimspa.com/main/cef.shtml>

<sup>50</sup> 21 U.S.C. § 343(s) (2005).

The DSHEA also requires that the labels are not mislabeled as to their contents. If an ingredient is listed in an “official compendium” but does not conform to the specifications of that compendium or if that ingredient is not listed in a compendium and either “fails to have the identity and strength that the supplement is represented to have” or “fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet” then it will be deemed misbranded and so be subject to sanctions by the FDA.<sup>51</sup> The DSHEA recognizes three such compendiums: The official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, and any supplement to these compendiums.<sup>52</sup> It is outside the scope of this paper to determine whether all of TrimSpa X32’s ingredients are in compliance with the labeling requirements (the author would need many more months to undertake a determination as to whether each bottle of TrimSpa X32 contains the ingredients in the type and quantity listed on the label). However, class action lawsuits have been filed in New York and California which allege that the manufacturer of TrimSpa EF (“EF” is an acronym for “ephedra free”) misrepresented the ingredients of the product and that the product does not actually contain *Hoodia gordonii*.<sup>53</sup> While TrimSpa EF is a separate product, the description of the product, and its endorsement by Anna Nicole Smith is quite similar to that of TrimSpa X32. Therefore, it is likely that TrimSpa X32 may face similar allegations of misleading and fraudulent labeling in violation of the DSHEA.

An additional labeling requirement is that the product must include the FDA two-part evaluation disclaimer.

TrimSpa X32 does include such a disclaimer and therefore is in compliance with this obligation.

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<sup>51</sup>21 U.S.C. § 343(s) (2005)

<sup>52</sup>21 U.S.C. § 321(j) (2005)

<sup>53</sup>*Garden State Briefs*, The Star-Ledger, February 26, 2004.



Finally, the DSHEA requires that the manufacturer complies with good manufacturing practice. However, I am unable to research whether TrimSpa X32 does or does not comply with this particular requirement.

### **III. Duty-to-Warn Litigation**

One must assume, even if based solely on a doctor's admonition in the *LA Times*, that the manufacturer of TrimSpa X32 is aware of Hoodia gordonii's effect on thirst. Further, studies have shown that glucosamine may affect insulin resistance and so have dire consequences for diabetics.<sup>54</sup> If this is the case, then it is possible for a user to allege that the manufacturer is liable in a failure-to-warn claim. If a user does die of dehydration due to his or her use of TrimSpa X32 or a diabetic is severely injured or killed due to the effects of glucosamine, it is conceivable to allege that the manufacturer is liable for the consumers' deaths. In order to prevail on such a claim, a plaintiff must successfully argue that the manufacturer failed to adequately warn the consumer of a product's risks and that failure to warn was the proximate cause of the plaintiff's injury.<sup>55</sup> It appears that there have been few duty-to-warn cases involving dietary supplements. Three cases were filed involving Metabolife's weight loss supplement product (which contained ephedra). However, the plaintiffs failed in all three cases.<sup>56</sup> Nevertheless, the failure of those cases does not foretell the failure of claims in the future and it is conceivable for a duty-to-warn case to succeed against the manufacturer of a

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<sup>54</sup>See, Beatrice Trum Hunter, *Nutritional supports for arthritis; Food for Thought*, Consumers' Research Magazine, February 1, 2004, at 8.

<sup>55</sup>Bernard J. Garbutt III and Melinda E. Hoffmann, *Recent Developments in Products Liability Law; Failure to Warn, the Learned Intermediary Defense, and Other Issues in the New Millennium*, 58 Food Drug L.J. 269 (2003).

<sup>56</sup>See, *Kemp v. Metabolife Int'l, Inc.*, 2004 U.S. Dist. LEXIS 18738 (E.D.La. 2004) (failed state law test of evidence of specific causation), *Rowe v. Metabolife Int'l, Inc.*, 2004 U.S. Dist. LEXIS 2453 (E.D.Pa. 2004) (dismissed on procedural grounds), *Lowe v. Metabolife Int'l, Inc.*, 206 F. Supp. 2d 1195 (S.D.Ala. 2002) (plaintiff's claim denied due to alternate means of compensation through state law).

dietary supplement.

#### **IV. Advertising**

TrimSpa's primary marketing conduits are television commercials and websites. In both mediums, TrimSpa promotes the X32 product through customer testimonials and celebrity endorsements. Further, the TrimSpa website provides a "consultation" service which helps consumers to choose which product best suits their lifestyle and weight-loss goals.

It is not within the resources of this paper to determine whether TrimSpa X32 fully complies with the FTC's requirement of substantiation for the product as a whole, because the author does not have access to TrimSpa's studies, if any, of the numerous ingredients in TrimSpa X32 touted to aid the consumer in losing weight. However, it is possible to question certain aspects of TrimSpa X32's primary (in terms of its prominence in TrimSpa advertising) ingredients. The FTC has already filed lawsuits against weight loss products, including Slim Down Solution, which contain glucosamine.<sup>57</sup> However, the advertisements for these products claimed to allow users to lose weight without changing their diet or lifestyle. In contrast, the website and television advertisements for TrimSpa X32 repeatedly encourage users to both reduce food intake and increase exercise in order to achieve maximum benefits. Therefore, it appears that TrimSpa X32 does comply with the truthfulness and nonmisleading advertising requirements of the FTC in this respect.

However, in the orders based on the its lawsuits against the weight loss products, the FTC prohibited

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<sup>57</sup>Phil Wallace, *FTC Enforcement Actions Follow Warnings on Claims; Dietary Supplements; Federal Trade Commission Pursues Slim Down Solution*, Food Chemical News, February 10, 2003, at 16.

defendants “from claiming, without competent and reliable scientific proof, that...D-glucosamine cause any weight loss at all.”<sup>58</sup> These orders signal that TrimSpa X32’s use of glucosamine may run afoul of the FTC’s substantiation requirement unless they can provide the existence of studies which are heretofore unknown to the FTC or manufacturers in the herbal weight loss supplement industry.

Further, it is doubtful that the manufacturers of TrimSpa or any similar weight loss product have conducted the studies necessary to comply with the FTC substantiation requirement for claims of the efficacy of Hoodia gordonii. As discussed above, there is a dearth of information about this ingredient aside from testimonials of users and small-scale unscientific studies.. Yet, the advertising for TrimSpa X32 is able to bypass the need to comply with the substantiation requirement because the advertisements do not provide claims as to the benefits or efficacy of Hoodia gordonii. On its website, the claims for Hoodia gordonii are simply that the ingredient “is a natural appetite suppressant, used for generations by South African tribesmen to stave off hunger during long hunting expeditions.”<sup>59</sup> Such a simple claim is easily substantiated, as that information has become public knowledge through a news segment on the television show, “60 Minutes.”<sup>60</sup> Because the advertising does not specify benefits of the ingredients, there is no necessity for substantiation.

MTV reality star Anna Nicole Smith provides a testimonial in television commercials for TrimSpa X32, claiming that the use of TrimSpa X32 helped her to lose several pounds and become a “starlet” once again. Numerous customers tout the great benefits achieved through the use of TrimSpa X32 on the product’s website, claiming losses of up to 130 pounds.<sup>61</sup> At first glance, a skeptic may conclude that the advertisements

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<sup>58</sup>*Slim Down Defendants Pay \$725,000*, United Press International, October 19, 2004.

<sup>59</sup><http://www.trimspa.com/main/cef.shtml>

<sup>60</sup>Lesley Stahl, *Hoodia; South-African Plant That May Help Fight Fat*, “60 Minutes”, CBS News Transcripts, November 21, 2004.

<sup>61</sup><http://www.trimspa.com/main/testimonials.shtml>

are blatantly misleading, presenting exceptions rather than examples of average weight loss results. However, based upon a strict reading of the FTC guidelines for dietary supplement advertising, the manufacturer of TrimSpa X32 appears to be both “truthful” and “nonmisleading.” The DSHEA two-part disclaimer appears both in the television commercials and at the bottom of the TrimSpa X32 website. Further, on each page of the website, there is a lengthy disclaimer which includes the DSHEA disclaimer and a statement that “[t]hese results are not typical. X32 may not work for everyone. Average weight loss achieved after 8 weeks using X32 with a reduced calorie diet and exercise was between .6 to .8 pounds per week based on the interim results of an ongoing clinical study.”<sup>62</sup> Further, it adds, “Consult physician before using. Read the label and follow directions. Do not use if pregnant or nursing. If you are allergic to shellfish, consult your doctor before taking glucosamine. Models have been compensated for photos and testimonials paid for commercial appearance.”<sup>63</sup> This lengthy disclaimer paragraph appears to alleviate any questions of misleading claims or statements made in the advertisements. Although the disclaimer is in smaller print than the rest of the page, the information is sufficiently legible and available to anyone reviewing the website.

While the testimonial section of the TrimSpa website and on the television commercials consumes a significant percentage of the advertising, the manufacturer of TrimSpa X32 does note directly in the testimonials that reduced food intake and increased exercise were a part of the consumer’s weight loss program. For example, one testimonial proclaims, “I found myself absolutely overcome with appreciation to TRIMSPA X32 and everyday found increased determination to keep going. I had the energy to eat right and make all the necessary changes to live healthier.”<sup>64</sup> The statements that diet and other changes contributed to the weight loss combined with the disclaimer which included expected weight loss by consumers expressly comply with

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<sup>62</sup> See, e.g., <http://www.trimspa.com>

<sup>63</sup> *Id.*

<sup>64</sup> <http://www.trimspa.com/main/testimonials.shtml>

the FTC's guidelines for customer testimonials.

The consultation section, displayed prominently in several different sections of the TrimSpa website, contains numerous disclaimers and recommendations that the consumer see a doctor and practice a healthy lifestyle.<sup>65</sup> This information appears to constitute truthful and nonmisleading information as to the effectiveness of the product and also serves as a disclaimer as to sole use of this product for significant weight loss results. Not only does the consultation section comply with FTC requirements but it serves as an aid to the weight loss claims appearing elsewhere on the website in ensuring that consumers are not misled by the efficacy claims made for the product.

## **CONCLUSION**

While TrimSpa X32 has hit the consumer market with a big splash of advertising, a million dollar giveaway and a celebrity endorsement, there remains a question of whether it should remain on the market. Under the DSHEA, it may continue to be on the market until the FDA provides substantiation as to its imminent danger to consumers. Until that time, TrimSpa X32 may legally be sold throughout the country. The product complies with all applicable FDA and FTC regulations and there currently appears to have no reason to force TrimSpa X32 from the store shelves. However, there remain significant questions as to the safety of

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<sup>65</sup> See, e.g., [www.trimspa.com/main/advice/trimspa2.cgi?page=12](http://www.trimspa.com/main/advice/trimspa2.cgi?page=12), [www.trimspa.com/main/advice/trimspa2.cgi?page=13](http://www.trimspa.com/main/advice/trimspa2.cgi?page=13)

the product. Its primarily touted ingredient, *Hoodia gordonii*, is relatively new to the Western World and there is little information about both its short-term and long-term effects on the body. While it may be safe for South African hunters, it is not necessarily safe to dieting Americans. There is an undisclosed risk for dehydration and perhaps other risks which are not presently known. Nevertheless, until the FDA can assume its burden of proof, there is nothing that regulators can do to pull the product out of the hands of consumers.